K111042 1/2

ATRICURE CRYO MODULE 510(k) SUMMARY

MAY 2 6 2011

General Information

Date Compiled	January 31, 2011
Classification	Class II
Product Code	GEH
Trade Name	AtriCure Cryo Module
Manufacturer	AtriCure, Inc 6217 Centre Park Drive West Chester, OH 45069
Contact	Rebecca Walters, RAC Regulatory Affairs Manager (513) 755-4576

Indications for Use

The AtriCure Cryo Module System is intended for use in the cryosurgical treatment of cardiac arrhythmias. The System consists of the AtriCure Cryo Module (ACM)—a non-sterile, reusable device—used with the Cryo1 cryo-ablation probe—a sterile, single use device—and/or the cryoICE cryo-ablation probe—a sterile, single use device.

Predicate Devices

The predicate devices for the AtriCure Cryo Module are the AtriCure frigitronics CCS-200 Cardiac Cryosurgical System (K811390) and the AtriCure Cryo1 cryo-ablation probe (K082074).

Device Description

The AtriCure Cryo Module (ACM) unit is a non-sterile reusable electro-mechanical and pneumatic cryogenic surgical system that delivers a cryogenic energy source, namely Nitrous Oxide, to a cryosurgical handpiece to create lines of ablation through cardiac tissue for the treatment of cardiac arrhythmias.

Materials

All materials used in the manufacture of the AtriCure Cryo Module are suitable for their intended use and suitable for use with pressurized nitrous oxide. The AtriCure Cryo Module is not intended for patient contact.

Testing

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices. Bench comparison testing, transit testing, electrical safety, electromagnetic compatibility, reliability testing, etc. were completed to show that the ACM is substantially equivalent and in conformance international standards and device specifications.

Summary of Substantial Equivalence

The AtriCure Cryo Module is equivalent to the predicate products. The intended use, method of operation, methods of construction and materials used, are substantially equivalent to existing legally marketed predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AtriCure, Inc.
c/o Mr. Mark Job
Third Party Official
Regulatory Technology Services LLC.
1394 25th Street NW
Buffalo, MN 55313

MAY 26 2011

Re: K111042
Trade/Device Name: AtriCure Cryo Module System (ACM, CRYO1 and cryoICE)
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: Class II (two)
Product Code: GEH
Dated: April 14, 2011
Received: April 15, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

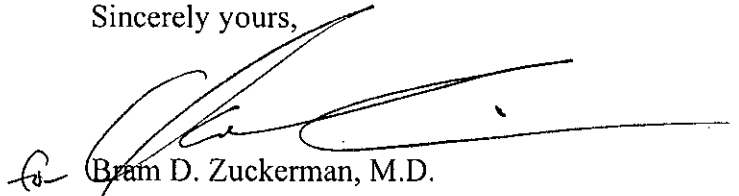
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K111042

Device Name: AtriCure Cryo Module

Indications for Use:

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Prescription Use X (Part 21 CRF 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CRF 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111042